

REMARKS

The Office Action mailed March 28, 2011 (hereinafter, "Office Action") has been reviewed and the Examiner's comments considered. Claims 1-44 are pending in this application. Claims 27-43 are withdrawn from further consideration as being drawn to a non-elected species. Claims 1 and 11 are amended herein. Applicants submit that no new matter is introduced.

Statement on Substance of Interview

A Telephonic Interview was conducted on April 18, 2011 ("Interview"). Participating in the Interview were Examiner Sarah K. Webb and the undersigned. Structural distinctions between the claimed invention and cited art were discussed. Proposed amendments were presented to further define the claimed structure. The Examiner offered recommendations for amendments to claim 1, which have been adopted herein to place the case in condition for allowance.

Response to Arguments

The Examiner helpfully provides a detailed response to Applicants arguments filed February 28, 2011. Applicants disagree with the conclusions drawn from certain interpretations of the independent claim 1 recitation, which was voiced in the Interview.

In particular, the Examiner states in the Office Action, "[t]he term 'form-fitted' is a product-by-process recitation that is not given patentable weight, as the process by which the product is made is not germane to the issue of patentability of the device itself. . . the Office Action considers junction (9) and sleeve (4) to be integral components, as the junction (9) forms the proximal end of the sleeve (4) and they are fixed to one another to operate as a single component. . . The manner in which the sleeve is fixed over the shaft is irrelevant to the issue of patentability of the structures of the claimed invention. The Keegan device provides all the structures required by the claims and performs the functions as claimed." (Office Action, p. 2.)

With respect to the contention that the term "form-fitted" is a product-by-process recitation, Applicants disagree because it provides for a unitary construction that is advantageous over the two-

piece construction of Keegan. However, in order to move prosecution forward, Applicants have amended claim 1 herein to remove the term “form-fitted” and add recitation directed to the proximal end of the sleeve. Keegan’s junction piece 9 is described as follows (emphasis added):

In this embodiment, a distal end face 61 of the junction piece 9 slopes proximally in a conical manner towards the U-shaped channel 33. This conical sloping arrangement assist in guiding the guidewire 10 towards the channel 33, as illustrated in FIGS. 13(a) to 13(c), thus minimising the possibility of misalignment occurring between the angled lumen 36 of the connector part 35 and the U-shaped channel 33.

(Keegan, paragraph [0183].)

Accordingly, Keegan does not show or describe a tubular constant diameter nose portion proximal of the radially inwardly tapering portion, the nose portion defining a proximal-most end of the sleeve, as recited in independent claim 1.

The Examiner cites case law in the Office Action, stating, “Additionally, it has been held that forming in one piece an article which has formally been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).” (Office Action, p. 3.)

Applicants respectfully submit that the *Howard* case is inapposite to the present analysis. In *Howard* three patents were invalidated by prior art. The patent in question (the third patent) was directed to a circular grate having a thin closed portion, a thick open portion, strengthened by ribs, and with a toothed periphery opposite the open part of the grate. The prior art patent described a grate with a closed back and open front, the open front being thicker than the closed back, such that a rib is formed on the closed back. The only difference between the prior art patent grate and the claimed grate is that the prior art grate was rectangular, to fit a rectangular fire box, while the claimed grate was circular, to fit a circular fire box. The grates were both used in cooking stoves. The prior art grate, being adapted for burning coal, was cast in two pieces, whereas the claimed

grate was cast in one piece. The court ruled that the difference was not patentable. The pending application is distinguished from the *Howard* analysis, for at least the reason that it involves the *elimination* of a prior art component. Differently from a grate that is attached by bolts or cast in one piece, as in *Howard*, the claimed delivery device is an assembly of numerous components. The claimed configuration enables the removal of one potentially problematic component from the prior art device. This is an important distinction due to the use of the claimed invention. Whereas *Howard* involved the use of grates for cooking stoves, the claimed delivery device is inserted into human bodies. Thus, the concerns for safety are greatly magnified. Such concerns and details thereof will be developed in a Declaration under 37 C.F.R. §1.132, if deemed necessary.

The Examiner also states, “Applicant argues that one of ordinary skill in the art would have been led away from extending the guide tube (101) proximally to overlap a length of the primary shaft (2) because it would have increased the diameter of the catheter. This is not found persuasive, because Keegan teaches that the length of the guidewire tubular means (101) of Figure 19a embodiment can be extended rearward (paragraph 202).” (Office Action, p. 3.)

Applicants’ argument with respect to a profile increase appears to be discounted here. It is inevitable, based on the Keegan disclosure, that extending proximally the guide tube 101 of FIG. 19(a) as suggested in the Office Action, would materially increase the catheter profile at the proximal end in order for the junction piece 9 to accommodate the guide tube 101. With respect to the allegation that a modification is taught by Keegan from the statement that the guide tube 101 can be extended rearward, Applicants reiterate that one skilled in the art would not be led to a configuration in which the guide tube 101 and catheter tube 2 overlap in length for at least due to the issue of increased profile (i.e., a rearward extension of the guide tube 101 would be accompanied by a respective lengthwise reduction of the catheter tube 2 in a proximal direction so that the connection piece diameter does not need to increase to accommodate the overlap).

Claim Rejections – 35 U.S.C. § 103

Claims 1-9, 11, 12, 15-20, 24-26, and 44 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over US 2003/0109886 to Keegan et al. (“Keegan”). Claims 21-23 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Keegan in view of US 2008/026506 to Griffin et al. (“Griffin”). Claim 10 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Keegan in view of USPN 6,945,989 to Betelia et al. (“Betelia”). Claims 13-14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Keegan in view of USPN 5,603,698 to Roberts et al. (“Roberts”). Applicants respectfully traverse these rejections.

Without conceding the propriety of the rejections or combinations of references, in the interest of compact prosecution, Applicants have amended independent claim 1 herein as discussed in the Interview. Accordingly, in view of the amendments and arguments presented herein, Applicants respectfully submit that independent claim 1, and claims 2-26 and 44 depending therefrom are patentable over the cited art. Applicants therefore request favorable reconsideration and withdrawal of the rejections under 35 U.S.C. § 103, and also request rejoinder of withdrawn claims 27-43.

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention. Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicant of additional or alternative distinctions between the

claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 50-2191, under Order No. 101671.0057P from which the undersigned is authorized to draw.

Dated: May 30, 2011

Respectfully submitted,

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